

| Notice of Allowability | Application No. | Applicant(s) | |
|-------------------------------|--------------------------|---------------------|--|
| | 09/664,519 | BARNEY ET AL. | |
| | Examiner Chih-Min Kam | Art Unit 1656 | |

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to 8/1/05.
2. The allowed claim(s) is/are 15,17-23 and 25.
3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some*
 - c) None
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other _____.

DETAILED ACTION

Status of the Claims

1. Claims 15, 17-23 and 25 are pending.

Applicant's amendment filed August 1, 2005 is acknowledged, and applicants' response has been fully considered. Claims 15 and 23 have been amended. Therefore, claims 15, 17-23 and 25 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 15, 17-23 and 25 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 5-6 in the amendment filed July 11, 2005.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard Roche on October 14, 2005.

Examiner's Amendment to the Claims:

Claims 15, 17, 21 and 23 have been amended as follows:

15. (Currently amended) A method for affecting the growth of *Staphylococcus aureus* in the vaginal area, said method comprising the step of: contacting the vaginal area with a compound selected from the group consisting of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids, and tetrahydroiso alpha salts, in an amount effective to kill, inhibit, or otherwise control the growth or proliferation of *S. aureus* in the vaginal area while allowing the growth of

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Lactobacillus in the vaginal area ~~at an acidic pH~~ wherein the concentration of the compound is in the range of from about 0.2 ppm to about 25 ppm.

17. (Currently amended) The method of claim 15, wherein the compound is placed in contact with the vaginal area using a product comprising of an absorbent material and the compound.

21. (Currently amended) The method of claim 20, wherein the compound is either in a douche or in a topical ointment.

23. (Currently amended) A product for affecting the growth of *Staphylococcus aureus* in the vaginal area, the product comprising an absorbent material, and a compound selected from the group consisting of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids, and tetrahydroiso alpha salts, in an amount effective to kill, inhibit, or otherwise control the growth or proliferation of *S. aureus* in the vaginal area while allowing the growth of Lactobacillus in the vaginal area ~~at an acidic pH~~ wherein the concentration of the compound is in the range of from about 0.2 ppm to about 25 ppm.

The following is an **Examiner's Statement of Reasons for Allowance:** The following references appear to be the closest art to the claimed invention. Nutter *et al.* (WO 98/11883) teach a method of killing cancer cells or bacterial cells, and/or inhibiting their growth through the use of beta acids (also known as lupulones) such as hexahydrocolupulone (HHC), and a pharmaceutical composition comprising the beta acid and a pharmaceutical carrier, which can be used as a topical ointment for topical administration to inhibit the growth of *Staphylococcus Aureus*; Todd *et al.* (U. S. Patent 5,082,975) teaches HHC at high concentration (50-200 ppm) inhibits the growth of certain lactobacilli. However, the two references either alone or in combination do not teach a product comprising an absorbent material and hop acids at concentration of about 0.2 ppm to 25 ppm, or a method of inhibiting the growth of *Staphylococcus Aureus* in the vaginal area using the hop acids in amount of about 0.2 ppm to 25 ppm. Therefore, the claims are allowable over the art of record.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.

CMK

Patent Examiner

CMK

October 14, 2005


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER